Tissue Containment

GOVERNANCE ADVISORY

Institutional Risk Review

Laparoscopic Morcellation Cancer Dissemination Risk

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Executive Summary

Laparoscopic morcellation remains an important tool in minimally invasive gynecologic surgery. However, when unsuspected uterine sarcoma is present, or when endometrial tissue is fragmented, tissue dissemination without effective containment may spread viable cells within the peritoneal cavity, potentially upstaging malignancy or increasing disease burden.

FDA-cleared containment systems specifically engineered for morcellation are currently available in the U.S. market.

Recent survey data and litigation history suggest variability in containment practices across institutions, including reliance on specimen retrieval bags not specifically cleared for morcellation.

For hospital leadership, this creates governance exposure in 4 key areas →

- Cancer Dissemination Risk
- Off-label Device Configuration
- Informed Consent Defensibility
- Documentation and VAC Oversight Gaps

This advisory outlines institutional considerations and governance safeguards.

Clinical Risk: Cancer Dissemination

- FDA analyses have estimated that unsuspected uterine sarcoma may occur in approximately 1 in 225 to 1 in 580 women undergoing hysterectomy or myomectomy for presumed benign fibroids, with earlier communications citing an estimate near 1 in 350.

- When morcellation is performed in such cases without effective containment, malignant or viable endometrial cells may be disseminated throughout the peritoneal cavity.

- Dissemination may result in:
  → Cancer upstaging
  → Altered treatment course
  → Potentially reduced long-term survival probability
  → Increased benign disease burden
  (e.g., parasitic fibroids or endometrial implantation)

- Containment integrity is therefore not merely a technical consideration, it is clinically consequential.

Governance Question:
Is the containment system used engineered and cleared for morcellation?

Regulatory & Device Clearance Landscape

- FDA has issued safety communications regarding morcellation.
- FDA-cleared containment systems for morcellation now exist.
- Some institutions continue to use specimen retrieval bags off-label.

Off-label physician use remains legally permissible.

However: When FDA-cleared alternatives are available, institutional review expectations may shift.

In litigation, plaintiffs' counsel may examine:

→ Availability of cleared systems

→ VAC review documentation

→ Rationale for off-label use

→ Standardization of containment protocols

Liability & Documentation Exposure

Common litigation focus areas:

- Was containment used?
- Was the device FDA-cleared for morcellation?
- Was rupture risk considered?
- Was cancer dissemination risk discussed?
- Is the containment device specified in operative notes?

Manufacturer liability protections may not extend in the same way when devices are used outside cleared indications, potentially shifting focus toward hospital oversight and surgeon documentation.

> If operative documentation lists only "specimen bag" without identifying device type or clearance status, **retrospective defensibility may be compromised**.

Informed Consent Risk

Under established informed consent doctrine:

Patients may (years) later ask:

- Was containment used?
- Was the containment system FDA-cleared?
- Was cancer dissemination risk discussed?

Most institutions do not maintain device-specific consent forms.

> **Governance consideration:**
> Does consent language reflect current risk landscape?

Practice Variability: A Governance Challenge

Survey data indicate:

- Variability in containment system selection
- Continued off-label or lack of bag use in some settings
- Inconsistent documentation of containment device type
- Reported containment bag rupture or compromise during morcellation procedures

Within a single health system, variability in containment selection may introduce variability in:

→ Oncologic risk

→ Risk of benign tissue dissemination (e.g., parasitic fibroids or endometrial implantation with increased disease burden)

→ Documentation defensibility

→ Institutional liability exposure

Governance Question:
Are containment decisions standardized or surgeon-dependent?

Why FDA Clearance Matters

FDA clearance for morcellation-specific containment systems indicates:

- Engineering validation for morcellation forces
- Labeling alignment with intended use
- Regulatory review of performance characteristics

Standardizing on FDA-cleared containment systems may:

- Simplify VAC defensibility
- Reduce documentation ambiguity
- Align with FDA safety communications
- Support institutional risk management

> Hospitals evaluating containment governance may consider whether **use of FDA-cleared systems** aligns with **patient safety** and institutional **risk objectives**.

Recommended Governance Actions

Hospitals may consider:

- Conducting formal VAC review of containment systems
- Documenting evaluation of FDA-cleared alternatives
- Standardizing operative documentation of containment device
- Reviewing consent language regarding cancer dissemination risk
- Reassessing morcellation policy every 2–3 years
- Engaging risk management and legal counsel in review

Ark Surgical's **LapBox®** is an **FDA-cleared containment system** specifically engineered for laparoscopic power and manual morcellation.

Disclaimer

This advisory is provided for educational governance purposes and does not constitute legal advice. Institutions should consult qualified legal counsel regarding specific liability considerations.

ONE-PAGE VAC CHECKLIST

Containment Governance Review – Laparoscopic Morcellation

Institution Name: _____

Date of Review: _____

Regulatory & Clearance Review
☐ Has the VAC evaluated FDA-cleared containment systems for morcellation?
☐ Is documentation of this evaluation on file?
☐ Does current policy reflect post-FDA safety communications?

Device Integrity & Performance
☐ Is the containment system engineered for morcellation forces?
☐ Has rupture performance data been reviewed?
☐ Is containment device selection standardized across surgeons?

Documentation
☐ Are operative reports required to specify containment device name?
☐ Is clearance status documented?
☐ Is configuration (contained vs. non-contained) recorded?

Informed Consent
☐ Does consent language address cancer dissemination risk?
☐ Is containment approach discussed with patients?
☐ Has legal counsel reviewed consent template in past 3 years?

Risk Management
☐ Has risk management formally reviewed morcellation containment policy?
☐ Has the policy been updated within the last 24–36 months?
☐ Has insurer guidance been considered?

Governance Status
☐ Containment policy aligned with FDA-cleared systems
☐ Containment policy under review
☐ Containment policy requires update